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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,562	09/04/2003	Sharon L. Bishop-Hurley	UVMO:022US	5742

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/655,562	BISHOP-HURLEY ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) *2-4,6-9,20-22,24-41 and 50-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,23,42-49,56 and 58-65* is/are rejected.

7)☒ Claim(s) *1,5,10-18 and 57* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20031120*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 2-4, 6-9, 20-22, 24-41, and 50-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and sequences. Election was made **without** traverse in the replies filed on May 13, 2005 and August 24, 2005.

Note that the dependencies of claims 20-41 appear to be incorrect. Claims 20-22 are dependent upon the first independent claim rather than upon independent claim 19. Claims 20-22 are thus identical in scope with claims 2-4. Claims 23-30, 33-36, 39, and 41 directly depend upon nonelected dependent claim 22 rather than upon independent claim 19.

Applicant's election without traverse of the invention of Group I and the peptide comprising SEQ ID NO:4 in the replies filed on May 13, 2005 and August 24, 2005 is acknowledged. The peptide comprising SEQ ID NO:4 has been examined and determined to be novel and unobvious over the prior art of record or any combination thereof. Accordingly, linking claims 47-49, 56, and 57, and claims 58-65, to the extent that they recite a peptide comprising SEQ ID NO:4, have been rejoined and examined with the elected invention.

Search and examination has not been extended to nonelected SEQ ID NOS:1-3 and 5-8. Note that the Office action mailed April 11, 2005 sets forth a restriction requirement among these SEQ ID NOS. There is no significant common sequence or structure among these claimed SEQ ID NOS, and each SEQ ID NO would require separate and non-overlapping sequence searches plus consideration of their results.

2. The Sequence Listing filed November 10, 2005 has been approved.

3. The disclosure is objected to because of the following informalities: In the first paragraph of the specification, the government rights sentence comes before rather than after the claim for

priority. See MPEP 310. SEQ ID NOS must be inserted after the amino acid sequences recited at page 32 of the specification. See 37 CFR 1.821(d). Appropriate correction is required.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 23, 42-49, and 58-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting or preventing the growth, preventing bacterial infection, preventing bacterial attachment, and identifying bacterial receptors where the bacteria are Staphylococcal or Haemophilus species, does not reasonably provide enablement for performing these functions for all bacteria. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150 (CCPA 1977) and have been adopted by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. With respect to (1), the nature of the invention is inhibiting or preventing the growth, preventing bacterial infection, preventing bacterial attachment, and identifying bacterial receptors for all bacteria. With respect to (2), the prior art does not disclose a peptide comprising SEQ ID NO:4.

The prior art also does not disclose any universal antibacterial substances, i.e. one that will bind to and/or inhibit the growth of all bacteria. With respect to (3), the relative skill of the art is high. With respect to (4), the predictability of the art is relatively low. One skilled in the art can not predict what antibacterial activity a compound may exhibit in the absence of testing. With respect to (5), the claims are relatively broad, embracing all types of bacteria, including gram-positive bacteria, gram-negative bacteria, etc. With respect to (6) and (7), other than tests with Staphylococcus aureus and Haemophilus influenzae, there are no working examples concerning other bacterial species. The specification does not give any direction or guidance as to how the claimed peptides can be used against bacteria which are unrelated to Staphylococcus or Haemophilus species. With respect to (8), given the breadth of the bacteria recited in the claims and given the expectation in the art that a compound effective against one or two species of bacteria would likely not be effective against large numbers of unrelated species, the quantity of experimentation necessary to use the invention would be vast. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

5. Claims 16, 43, and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent claim 1 recites peptides comprising at least 15 amino acids. However, dependent claim 16 recites a peptide having a lower length limitation of "about 15" residues. It is not clear if certain amino acids specified in the SEQ ID NOS recited in the independent claim can be omitted in order to achieve the lower length limitation recited in the dependent claim. Alternatively, it is possible that the word "about" should be deleted from

before "15" in claim 16 and inserted before "25". Compare, e.g., claim 15. Claims 43 and 44 are indefinite because they recite a method of preventing bacterial growth in a solution or on an abiotic surface, but define the amount of peptide to be used functionally with respect to an in vivo use of the peptide. It is not clear if the claim unintentionally recites an incorrect functional test of peptide amount, or if the claim intends to use an unrelated functional test to define the amount of peptide used in the recited methods.

6. Claim 10 is objected to because of the following informalities: In claim 10, "Staphylococcal" is misspelled. Appropriate correction is required.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

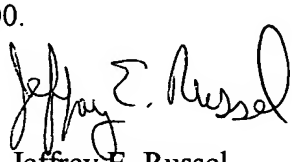
8. Claim 56 is rejected under 35 U.S.C. 102(b) as being anticipated by Tempst et al (U.S. Patent No. 5,466,671). Tempst et al teach antibacterial peptides which are active agent H. influenzae. See claim 13. Sufficient evidence of similarity is deemed to be present between the peptides of Tempst et al and Applicants' claimed peptide to shift the burden to Applicants to provide evidence that the claimed peptide is unobviously different than the peptides of Tempst et al. Note that process limitations do not impart patentability to product-by-process claims where the product is otherwise anticipated by the prior art.

9. Claims 1, 10-18, and 57 are objected to because of their recitation of nonelected sequences, but would be allowable if re-written to recite only the elected sequence. Claim 5 is objected to as being dependent upon an objected base claim, but would be allowable if rewritten

in independent form including all of the limitations of the base claim and any intervening claims. The prior art of record does not teach or suggest peptides comprising SEQ ID NO:4. Accordingly, methods of using the peptide, and medical devices comprising the peptide, would also be novel and unobvious over the prior art of record.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

June 9, 2006